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K042023

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FUJIFILM MEDICAL SYSTEMS USA, INC.

419 WEST AVENUE
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510(K) Summary

In accordance with the requirements of the Safe Medical Device Act, FUJIFILM Medical Systems, USA, Inc. herewith submits a 510(K) summary of safety and effectiveness for the following device.

SUBMITTER NAME / ADDRESS:	FUJIFILM Medical Systems, USA, Inc. 419 West Avenue Stamford, CT 06902
CONTACT PERSON / TEL NO:	Frank Gianelli Regulatory Coordinator
DATE SUMMARY PREPARED:	June 29, 2004
ESTABLISHMENT NO.:	2443168
TRADE/PROPRIETARY NAME:	Fuji Computed Radiography (FCR) ClearView CS Image Reader (CR-IR363)
COMMON/USUAL NAME:	Computed Radiography Image Reader
CLASSIFICATION NAME:	Solid State X-Ray Imager
CLASS/PANEL:	Class II, 90-MQB, 21CFR 892.1650
PREDICATE DEVICE(S):	FCR 9000HQ Image Reader FCR 5501D Image Reader FCR 9000 Image Reader

DEVICE DESCRIPTION:

A Fuji Computed Radiography (FCR) system typically consists of an image reader (IR), patient ID terminal, imaging plates (IPs), IP cassettes, interface board, positioning monitor, laser printer for hard copy output, and optionally an image workstation, optical disk file, and network interface. **This notification is for the image reader and associated imaging plates (IPs).** IPs are used as two-dimensional radiation detectors in place of radiographic film and intensifying screens to capture a portion of the projected x-ray patient image. In the image reader, the captured image data is associated electronically with patient and exam identification data and the latent image is read by laser emission by the phenomenon of photostimulable luminescence. The photostimulated luminescence is then collected, detected, sampled, and digitized. The image data is then digitally processed according to exam and user-specified parameters and may be displayed on a CRT monitor to confirm patient positioning, printed by a hard copy device (such as laser printer, or dry printer), or output to a workstation, optical disk file, or other destination. The device performs no lossy compression of image data.

FCR ClearView CS consists of an Image Reader and Imaging Plates of various sizes and types (described below). The Image Reader is cassette-based. The IP is placed into a cassette and exposed using standard x-ray equipment. The cassette containing the exposed image plate is then manually inserted into the ClearView CS Image Reader. The image reader automatically removes the IP from the cassette and moves the IP to the reading position where it is scanned by a laser beam. The luminescence from the IP is then converted to an electrical signal by a photoelectron multiplier

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tube and then converted to a digital signal. After reading, the IP is erased, and reloaded into an empty cassette for subsequent exposure again.

As with other FCR image readers, the FCR ClearView CS will feature photostimulable phosphor imaging plates (IP) composed of europium activated barium fluorohalaid compounds in a crystal form held in an organic binder. The IP has a rigid substrate, which enables it to be held in a constant plane. The ClearView CS uses three types of IPs: type HR-BD for high resolution dual-side reading, type HR-V for high resolution reading, type ST-VI for standard resolution reading

INTENDED USE:

The indications for use of the Fuji Computed Radiography (FCR) ClearView CS Image Reader (CR-IR363) with Image Plate (IP) reading is the identification, capture, digitization, and processing of diagnostic x-ray images, and associating patient and exam identification with the images.

TECHNOLOGICAL CHARACTERISTICS:

The Fuji ClearView CS image reader is considered comparable and substantially equivalent to the Fuji FCR 9000HQ Image Reader, Fuji FCR5501D Image Reader and the Fuji FCR 9000 Image Reader.

PARAMETER	FCR ClearView CS		FCR 5501D		FCR 9000HQ		FCR 9000	
Image Recording								
Patient Identification	Digital Data (from Console)		Digital Data (from Console)		Digital Data (from Console)		Digital Data (from Console)	
Recording Method	Photostimulable Luminescence		Photostimulable Luminescence		Photostimulable Luminescence		Photostimulable Luminescence	
No. of Imaging Plates/Cassette Slots	Four Cassette slots		Two Built-in Imaging Plates		One Cassette slot		One Cassette slot	
Image plate types and sizes	ST-VI 14"×17", 14"×14", 10"×12", 8"×10"		ST-55BD 460x510 mm (usable area)		ST-VN 14"×17", 14"×14" 10"×12", 8"×10"		ST-VN 14"×17", 14"×14" 10"×12", 8"×10"	
	HR-V 24cm×30cm, 18cm×24cm				HR-V 8"x10"		HR-V 8"x10"	
	HR-BD 24cm×30cm, 18cm×24cm							
Image Reading								
Reading Method	Raster Scan (ST/HR). Raster Scan with dual-side detector(HR-BD)		Raster Scan with dual-side detector		Raster Scan		Raster Scan	
Reading Laser	Laser Diodes (660 nm)		Laser Diodes (680 nm)		Laser Diodes (675 nm)		Laser Diodes (675 nm)	
Gray Scale	10 bits (1024 gray levels)		10 bits (1024 gray levels)		10 bits (1024 gray levels)		10 bits (1024 gray levels)	
Sampling Raster	IP Reading Area	Pixels/mm	IP Reading Area	Pixels/mm	IP Reading Area	Pixels/mm	IP Reading Area	Pixels/mm
	ST-VI 14"×17"	10	ST-55BD 17x17 in	10	ST-VN 14"×17"	10	ST-VN 14"×17"	5
	ST-VI 14"×14"	10	ST-55BD 14x17 in	10	ST-VN 14"×14"	10	ST-VN 14"×14"	5
	ST-VI 10"×12"	10	ST-55BD 14x14 in.	10	ST-VN 10"×12"	10	ST-VN 10"×12"	6.7
	ST-VI 8"×10"	10	ST-55BD 10x12 in	10	ST-VN 8"×10"	10	ST-VN 8"×10"	10
	HR-V 24cm×30cm	10	ST-55BD 8x10 in	10	HR-V 8"×10"	10	HR-V 8"×10"	10
	HR-V 18cm×24cm	10	ST-55BD 18x43 cm	10				
	HR-BD 24cm×30cm	20						
	HR-BD 18cm×24cm	20						
Physical								
W×H×D (mm)	655×740×1480 mm		1170x800x1800		950×750×1760 mm		950×750×1760 mm	
Weight (kg)	285 kg		540 kg		350 kg		350 kg	
Throughput (Approximate)	122 IP's/hr		150 IP's/hr		75 IP's/hr		110 IP's/hr	
Processing Time - 14"×14" IP	53 seconds		88 seconds		142 seconds		105 seconds	

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

FUJIFILM Medical Systems USA, Inc.
% Mr. William J. Sammons
Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive, P.O. Box 13995
Research Triangle Park, NC 27709-3995

AUG 23 2013

Re: K042023
Trade/Device Name: Fuji Computed Radiography (FCR) Clear View CS Image Reader (CR-IR363)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: August 10, 2004
Received: August 11, 2004

Dear Mr. Sammons:

This letter corrects our substantially equivalent letter of August 25, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

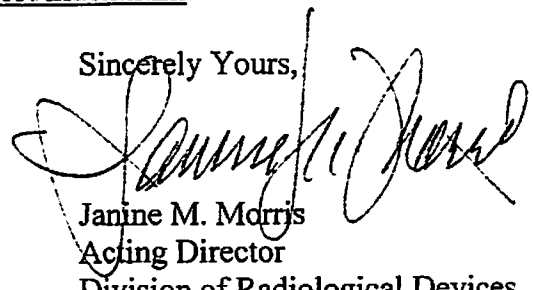
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K042023

Device Name: FCR ClearView CS Image Reader (CR-IR363)

Indications For Use:

The indications for use of the Fuji Computed Radiography (FCR) ClearView CS Image Reader with Image Plate (IP) reading is the identification, capture, digitization, and processing of diagnostic x-ray images of the human body, and associating patient and exam identification with the images.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042023